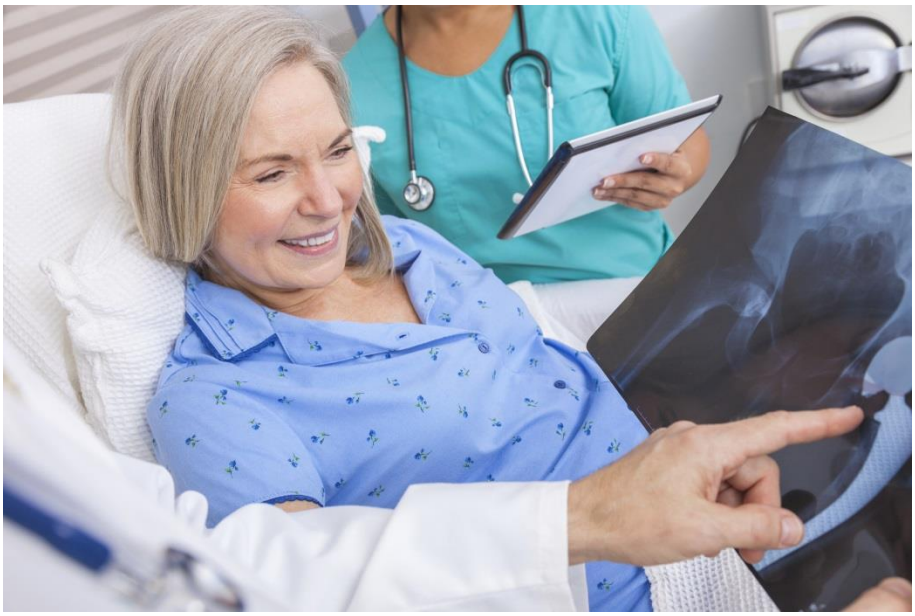
Australian Government

The safety of Australian patients comes first

An Action Plan for Medical Devices

Improving Australia's medical device regulatory framework



Australian Government
Department of Health
Therapeutic Goods Administration

AUSTRALIA'S REGULATORY SYSTEM

The regulatory requirements for medical devices in Australia are some of the most stringent in the world. Compliance by industry with these requirements is never optional or voluntary. The obligations are based on globally aligned requirements that regulate different products according to their risk. While Australia recognizes evidence provided to other international regulatory agencies, the Therapeutic Goods Administration (TGA) carries out additional reviews for medium and high risk devices.

Medical device regulation in Australia is based on scrutiny of the products before they are approved for the market, surveillance of products once on the market and compliance and enforcement activities. The TGA has a range of powers including compelling sponsors to provide information, suspending or cancelling supply or legal actions such as civil and criminal penalties if requirements are not met.

The level of review prior to the TGA approval depends on the risk that the medical device presents to patients or the end user. The approach balances the need to provide patients and the healthcare system with timely access to innovative new technologies with the appropriate level of scrutiny for product safety, performance and effectiveness.

Medical devices are categorized based on their risk, with more evidence required for higher risk medical devices such as pacemakers and joint replacements; and less evidence for lower risk medical devices like bandages and tongue depressors. The risk based classification system is used by international regulators including the United States, the European Union, the United Kingdom, Canada and Japan.

However more can be done to strengthen and improve Australia's medical device regulatory system and patient safety. Transparency can also be significantly improved. More information on individual medical devices can also be made available to users of medical devices, their families and healthcare professionals to help make informed decisions on the use of particular products.

Our current system

* Risk based
* Global principles
* But with extra assurances

* Pre-market assessment
* Ongoing surveillance
* Compliance checks
* Enforcement for non-compliance

There is room, however for further safeguards

ACTION PLAN

This Action Plan is a three part strategy to strengthen Australia's regulatory system whilst continuing to be patient focused and have greater transparency. It outlines actions that continue to improve the safety, performance and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. The Action Plan will:

- ✓ **Strategy 1:** Improve how new devices get on the market
- ✓ **Strategy 2:** Strengthen monitoring and follow-up of devices already in use
- ✓ **Strategy 3:** Provide more information to patients about the devices they use.

The Action Plan describes:

- a number of reform activities currently underway that the TGA will implement sooner; and
- additional ways to improve transparency and to increase public confidence in Australia's medical device regulatory system. The TGA will actively seek feedback on new ways to do these.

There will be open public consultations to seek feedback on proposed policies, regulations and the guidance materials developed. Decisions on specific policies and regulations will need to be made by the Government or by the Federal Parliament (if particular laws require change).

The TGA has been tasked to implement the Action Plan. The TGA will develop a separate document that provides more detail about the Action Plan, including more detail on proposed actions and activities. Collaboration with stakeholders including consumer groups on approaches for implementing the strategies is central. The TGA will work closely with consumer groups to develop a range of consumer focused documents that explain the options for further improvements to medical device regulation.

The Action Plan

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Strategy 1
Improve how new devices get on the market

Strategy 2
Strengthen monitoring and follow-up of devices already in use

Strategy 3
Provide more information to patients about the devices they use

The TGA will ensure that all perspectives, but particularly of those consumers who use medical devices, are taken into account. Public reporting by the TGA will ensure that progress against this Action Plan is transparent to all.

STRATEGY 1: Improve how new devices get on the market

What happens now?

Every medical device must meet a set of requirements (called **'Essential Principles'**) before they can be approved for supply in Australia. To meet the Essential Principles, manufacturers must provide evidence, including clinical evidence on matters such as:

- Safety requirements
- The chemical, physical and biological properties the device must have
- Protection from infection and microbial contamination
- Appropriate construction and environmental properties
- Information that must be supplied with the medical device

For very low risk devices, a manufacturer can self-certify that their device meets the Essential Principles. For all other devices, a qualified body must assess the device and this evidence is used to show that the device meets the Essential Principles. This assessment (known as conformity assessment) can either be carried out by the TGA or a recognised qualified overseas body. Some medium risk devices are subject to further assessments by the TGA. Depending on the product, high risk devices either must be assessed by the TGA or be subjected to a detailed audit (review in addition to the reviews already done in Europe) by the TGA prior to supply in Australia.

What is proposed?

The TGA will strengthen its assessment processes and oversight of how devices are approved for use in Australia. The TGA will review whether the current processes around industry self-certification of low risk devices are appropriate.

With the fast-paced increase in the numbers of medical devices with software or digital components, the coverage of regulation in Australia will be broadened to ensure new and emerging technology such as 3D printed devices and software apps are safe and provide reliable information to consumers. The TGA will establish a specialist unit to better evaluate emerging technology such as 3D printed devices and software apps, as poorly performing apps may pose a significant consumer risk. It will examine ways to better monitor device cybersecurity risks. The TGA will provide clearer guidance to industry on cybersecurity requirements for medical devices and the IT systems they connect with.

Potential changes, to add further rigour to the assessment of medium and higher risk devices will be publicly consulted on before final decisions are made by the Government. The TGA will seek stakeholder views on whether more applications for medium risk devices should require mandatory audits by the TGA before being marketed in Australia. The TGA will also review the arrangements for medical devices that are used in clinical trials to ensure the use of these devices meet community expectations. In parallel, the TGA will publish clearer guidance documents so that all Australians and in particular, industry understands the regulatory requirements before particular types of medical devices can be marketed in Australia. This includes first aid kits and single use procedure packs in surgery, and specific devices such as contact lens, lasers, brain stimulators and dermal fillers.

For higher risk devices, the TGA will consult on whether the Government should require greater levels and scrutiny of clinical evidence for certain groups of devices. These devices include spinal implants, devices that make diagnoses, diabetes management devices, medical devices used for IVF, and companion diagnostics (tests used to guide the choice of medicines for particular cancers or rare diseases).

Direct input from consumers on these actions will assist in designing how the Strategy will be implemented.

Strategy 1

More rigour in assessment processes

More reviews of low and medium risk devices

Higher level scrutiny of clinical evidence

Ensure new and emerging technologies are safe

Actions

Early-mid 2019: Identify options for increasing oversight of the evaluation and market approval process for particular devices.

Early-mid 2019: Conduct public stakeholder consultations on proposed regulatory changes and guidance materials.

Mid-late 2019: Consult with stakeholders on proposed changes that affect change industry fees and charges or change the regulatory burden on healthcare professionals of industry.

Mid 2019: Establish a specialist unit in the TGA to increase capacity in assessing and monitoring digital health.

End 2019: Draft regulatory changes as agreed by the Government.

End 2019: Increase the capacity of the TGA medical device review teams.

STRATEGY 2: Strengthen the monitoring and follow-up of devices already in use

What happens now?

The TGA monitors the safety and performance of medical devices after they have been approved and made available to Australian patients. The TGA uses a wide range of sources of information, including the mandatory reporting of adverse events by industry, voluntary reporting from the public and from health care professionals and communications from other regulators. The TGA also analyses the medical literature and carries out post market reviews. However many incidents are not currently reported by private or public hospitals or by individual healthcare professionals. Recent incidents involving medical devices such as transvaginal mesh have highlighted the need to access more complete data on adverse events and rapidly to share information about emerging safety issues to more promptly address threats to patient safety and to take quicker action.

What is proposed?

The TGA will accelerate implementation of medical device reforms announced from the Expert Panel Review of Medicines and Medical Devices Regulation. The TGA will introduce systems to improve its ability to identify problem medical devices earlier and to take action quicker. The new systems will also enable the TGA to confirm with other, international regulators whether they have also had significant reports of adverse events with particular products. The TGA's IT systems and analysis capability for adverse events will be enhanced to improve our assessment and investigation processes. Together with health consumer organisations, we will also develop simpler ways for consumers to report adverse events (including using smartphone apps) and publicise how reporting of adverse events can improve the safety of products.

The TGA will work closely with healthcare facilities and state and territory health departments to find ways to increase rapid information sharing about medical device safety and effectiveness. This may include developing education programs and systems to help healthcare professionals and hospitals identify and report medical device incidents. We will also review any regulatory or legal barriers that may currently compromise the ability of the TGA to respond quickly to device safety reports received from hospitals.

To increase the extent and timeliness of adverse event reports, the TGA will consult publicly on options for:

- whether it should be mandatory for healthcare facilities to report adverse events/safety problems with medicine and medical devices to the TGA;
- removing some existing exemptions to require more timely and improved reporting of adverse events by industry to the TGA; and

- whether the TGA should have enhanced powers for recalls and other powers relating to cancelled devices.

Better tracking and traceability of medical devices throughout the healthcare supply chain and to patients is also a high priority. Following wide public consultation, the TGA will provide advice to the Government on the feasibility of requiring a Unique Device Identifier system to achieve better tracking of devices. This would mean that patients will be able to know much more about the particular device they have implanted or treated with.

After consultation with stakeholders, the TGA will assess options to increase its inspection program of medical device manufacturing sites to confirm ongoing quality in manufacturing medical devices. Increasing the frequency of manufacturer inspections of certain high risk devices and new onsite auditing of their reporting of adverse events will also be explored.

Consumers and consumer organisations will have direct input on how these actions will be implemented.

Actions

Early 2019: Establish a working group with state and territory health departments and the Australian Commission on Safety and Quality in Health Care.

Mid 2019: Consult publicly on proposed changes to adverse event reporting requirements and systems and strengthened tracking of devices in the healthcare system.

Mid 2019: Consult publicly on proposed changes that potentially incur a change in fees or charges and/or regulatory burden**.**

Mid-late 2019: Consult with consumer groups, healthcare industry representatives on opportunities for collaboration and proposed changes.

Early 2020: Government to introduce legislation to implement agreed regulatory changes.

Strategy 2

Scope the introduction of unique device identifiers

Enhance inspections and reviews to confirm ongoing quality and safety

Explore removing reporting barriers including potential of mandatory reporting of adverse events by healthcare facilities

Greater data analysis, information sharing and joined up systems with hospitals

STRATEGY 3: Provide more information to patients about the devices they use

What happens now?

The TGA provides information on its website about a range of regulatory responsibilities. However the information is often not easy to navigate or understand given the technical language that is used. Social media is also used by the TGA and an information enquiries service is in place to answer specific questions from the public, healthcare professionals and industry. Despite this, there is a very low level of consumer awareness about the TGA and the medical device regulatory system.

For many years, Consumer Medicine Information documents have been required to be made available for prescription medicines but there are not corresponding information sources for many medical devices. In addition, while the TGA publishes a document called the "Australian Public Assessment Report" explaining the factors behind the decision to approve or reject each new prescription medicine, there is not currently a similar public document made available for new high risk devices. Consumers report that it is hard to find information on medical devices, difficult to report adverse events and that the TGA information on medical devices is not in a format that is easily accessible, user friendly or searchable.

What is proposed?

Recent media has raised patient concerns about the safety of medical devices and more broadly, the lack of public information available about the regulatory framework for devices in Australia. The TGA will partner with consumer groups to co-design a strategy to raise awareness about the regulatory system as well as about how regulatory decisions were reached about individual products, in particular higher-risk devices. This will include publication of consumer-friendly information on each new higher-risk device.

We will also strengthen consumer awareness of the responsibilities of the TGA, suppliers of medical devices and health professionals through a range of new consumer communication and education programs. For example, the requirements of manufacturers to provide consumer information leaflets and implant cards for implanted medical devices will be widely publicised and monitored for compliance. Healthcare facilities will be encouraged to ensure patients are aware of these materials.

The TGA will seek feedback on options to publish more information on how regulatory decisions are reached for individual higher risk devices, including publishing clinical evidence, searchable incident reports, manufacturers' inspection reports and regulatory actions on individual devices.

To assist in monitoring those medical devices already in use, the TGA will encourage greater reporting of adverse events by patients by working collaboratively with consumer advocacy and support groups to identify mechanisms that consumers find easier to use.

The TGA will also publicly report on assessment timeframes for new products to demonstrate that assessments support timely access by consumers.

In addition to the existing Advisory Committee on Medical Devices, the TGA will establish expert working groups with consumer representation and co-chairing to provide advice and feedback on devices of concern. This will include a women's health products working group, and possibly other groups for particular product types or technologies.

Direct input from consumers on these actions will be a core component of how the strategy will be implemented. In addition, the TGA and consumer organisations will co-design a range of consumer friendly documents. These should help translate technical regulatory language into plain English and make documents more accessible to non-expert audiences.

Actions

Mid-late 2019: Consult with consumer advocacy, support groups and industry on proposed changes to transparency.

Mid-late 2019: Publish regulatory assessment timeframes.

Late 2019: Government decision on any changes to regulations required to support publication of additional information on medical devices.

End 2019: Establish new consumer working groups and publish their Terms of Reference.

Strategy 3

Publish more information about decisions made and the medical device products regulated by the TGA

Strengthen consumer awareness of how safety and performance of medical devices are assessed

Find and implement ways to help consumers report adverse events more easily

Establish expert groups with consumer representation

Therapeutic Goods Administration

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